K050798

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15 510(k) Summary

AUG 15 2005

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of CFR 807.92.

Name:	Howard Bailin Vice President, C.O.O.
Address:	Axon Systems, Inc. 400-2200 Oser Ave Hauppauge, NY 11788
Phone:	631 436 5112
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Email:	hbailin@axonsystems.com
Proprietary Name:	Eclipse Neurological Workstation Eclipse Lite Neurological Workstation
Common Name:	Electroencephalograph (EEG Monitor), Evoked Potential (SEP, BAEP, AEP, VEP, MEP) System, EMG Monitor
Classification Name:	Electroencephalograph, Evoked Response, Electromyograph
Classification:	Class II (Performance Standards) Panels: Neurology, Anesthesiology Number: 882.1400 Electroencephalograph 882.1420 Electroencephalograph (EEG) Signal Spectrum Analyzer Electromyograph Monitor Stimulator, Electrical, Evoked Response Stimulator, Photic, Evoked Response Stimulator, Sonic, Evoked Response Procodes: GWQ, GWS, GWF, GWE, GWJ, CAB
Predicate Devices	Axon Systems – EpochXP (K032741) Digitimer – D185 (K020400) NuVasive – Neurovision JJB (K032083) Grass Telefactor – AS40 Amplifier (K021807)

Description:	The Eclipse Neurological Workstation provides continuous monitoring of brain and neural pathways intraoperatively or in the intensive care unit. The system has been designed to meet the requirements for comprehensive neurological monitoring in the operating room and critical care areas. The Eclipse Neurological Workstation can be used to monitor neurological data using either individual or multimodality EEG, EMG and evoked potential test protocols. The main Eclipse system components include: computer, controller, digital preamplifiers, direct nerve, sensory and motor evoked potential electrical stimulators, stimulator extension modules, LED goggles and insert earphones. The Eclipse also provides support for the Nonin XPod pulse oximeter module and high impedance preamplifier module to allow recording from high impedance electrodes. Recording electrodes detect spontaneous or stimulus evoked electrophysiological activity and are used as inputs to the digital preamplifier. The electrophysiological signals are amplified, filtered, optically isolated and digitized. The digitized data is then routed to the digital signal processor (DSP) located in the Eclipse controller. The DSP processes the data and controls timing for the electrical, audio and visual stimulators. The computer controls the user interface for setting parameters and the display of processed data. A built-in pulse oximeter provides pulse rate and oxygen saturation measures. Data from external devices, such as vital signs or other physiological monitors, can be imported to the Eclipse display screen, allowing the operator to correlate changes in neurological function with the patient's systemic measurements. In addition, a display window may be opened to observe the surgeon's microscope view or other video input. The Eclipse is network compatible for data review within the hospital and permits secure information access over the Internet. Based on the technical information provided in this 510(k) and the safety and effectiveness criteria of the design and development process, validated and verified, we claim the Eclipse Neurological Workstation to be safe, effective and substantially equivalent to the predicate device(s) noted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2005

Mr. Howard Bailin
Vice President, C.O.O.
Axon Systems, Inc.
400-2200 Oser Avenue
Hauppauge, New York 11788

Re: K050798
Trade/Device Name: Eclipse Neurological Workstation
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: II
Product Code: GWF
Dated: August 1, 2005
Received: August 2, 2005

Dear Mr. Bailin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Bucher for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050798

Indications for Use Statement

510(k) Number K050798

Device Name **Eclipse Neurological Workstation**

Indications for Use

The Eclipse neurological workstation is intended for use to monitor sensory and motor pathways in the operating room and critical care areas. The instrument uses electroencephalography (EEG), electromyography (EMG), motor and sensory evoked potentials and nerve potentials to provide health care professionals with information to help assess a patient's neurological status. Transcranial stimulation techniques for motor evoked potentials are used to assess for acute dysfunction in axonal conduction of the corticospinal tract.

Prescription Use ___X____ AND/OR Over-The-Counter Use ________
(Part 21 CFR 801 Subpart D)

Barbara Buehler for Mkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050798